

**Promoting Physical Activity in Latinas via Interactive Web-based Technology**

**NCT03491592**

**6/16/25**



**BROWN UNIVERSITY**  
**CONSENT FOR RESEARCH PARTICIPATION**

Pasos Hacia La Salud  
Promoting Physical Activity via Interactive Web-Based Technology  
[Version 2, 12/6/2018]

**KEY INFORMATION:**

You are invited to take part in a Brown University research study. Your participation is voluntary.

- **PURPOSE:** The purpose of this study is to help us learn more about promoting good health among Latinas.
- **PROCEDURES:** You will be asked to attend an orientation session, first visit, and second visit, before enrolling in the study. We also ask that you return to our office again at 6, 12, 18 and 24 months.
- **TIME INVOLVED:** You will be in the study for 24 months. The first phone interview will be 15-30 minutes. Each of the following visits will be 60-90 minutes. There are 7 visits total throughout the 24 months. You will also have 15 – 20 minute phone calls with study staff 6-8 times throughout the study.
- **COMPENSATION:** You may receive up to \$310.
- **RISKS:** Participation in this study may involve some added risks or discomforts due to increasing your level of physical activity.
- **BENEFITS:** You will receive information about physical activity or other health behaviors. You may increase your health knowledge and become motivated to exercise more.
- **ALTERNATIVES TO PARTICIPATION:** If you choose to not participate in this study, you are still free to participate in other health promotion programs in the community. You may also choose to learn more about exercise on your own.

**1. Researchers:**

Principal Investigator: Dr. Bess Marcus  
Telephone Contact: (401) 863-9858

Project Coordinator: Rachelle Edgar  
Telephone Contact: (401) 863-6164

**2. What is this study about?**

The purpose of this study is to help us learn more about promoting good health among Latinas. We will ask you to take part in one of two physical activity programs and answer questions, so we can learn how much the program helped you. These physical activity programs will be called 'Physical

Activity Program 1’ and ‘Physical Activity Program 2.’ With this information, we hope to design better ways of providing health information to Latinas.

You are being asked to be in this study because you are a Latina woman between the ages of 18 to 65.

**3. What will I be asked to do?**

**4. Will I be paid?**

| <b>Study Step</b>                | <b>Task for Participant</b>                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Time Commitment</b> | <b>Incentive/Reimbursement<br/>(Paid in cash)</b>                                                                                                        |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Telephone Survey                 | -Answer questions by phone with staff member                                                                                                                                                                                                                                                                                                                                                                                                               | 15-30 minutes          | n/a                                                                                                                                                      |
| Orientation Visit                | <ul style="list-style-type: none"> <li>- Learn more about the study</li> <li>-Sign consent form</li> <li>-Complete web and text access test</li> <li>-Measure height, weight, and blood pressure</li> <li>- Complete surveys</li> <li>-Receive packet of surveys to complete at home and bring to next visit.</li> </ul>                                                                                                                                   | 1 hour                 | \$10 for travel costs<br><br>Child care reimbursement:<br>\$7/hour 1 child, \$10/hour<br>2+ children (max of 2 hours)                                    |
| Measurement Visit                | <ul style="list-style-type: none"> <li>-Return completed survey packet</li> <li>-Measure your waist circumference, blood pressure and body fat.</li> <li>-Complete surveys about health behaviors.</li> <li>-Receive activity monitor and instructions to wear for 7 days.</li> </ul>                                                                                                                                                                      | 45 minutes             | \$10 for travel costs<br><br>Child care reimbursement:<br>\$7/hour 1 child, \$10/hour<br>2+ children (max of 2 hours)                                    |
| Baseline/<br>Randomization Visit | <ul style="list-style-type: none"> <li>-Return activity monitor and log</li> <li>-15 minute walk to demonstrate moderate intensity physical activity. We will also monitor and record your heart rate.</li> <li>- Complete surveys about health behaviors.</li> <li>- You will be randomly assigned to one of the two physical activity groups.</li> <li>-A staff member will show you how to use the study website and other study components.</li> </ul> | 2 hours                | \$10 for completing surveys<br><br>\$10 for travel costs<br><br>Child care reimbursement:<br>\$7/hour 1 child, \$10/hour<br>2+ children (max of 2 hours) |
| Check-in Calls                   | - Staff member will call to answer questions and                                                                                                                                                                                                                                                                                                                                                                                                           | 5-15 minutes           | No incentive                                                                                                                                             |

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|                                                              | <p>help you set physical activity goals.</p> <p><b>For Group 1:</b> Calls at week 1, month 1 and 9</p> <p><b>For Group 2:</b> Calls at week 1, and months 1, 2, 3, 9, 15, 18, 21</p>                                                                                                                                                                                                                                                                                          |               |                                                                                                                                                                                                                                                                                                                   |
| <p>Use the study website</p> <p>Complete monthly surveys</p> | <p>-Log onto study website once a month to complete surveys.</p> <p>-Log onto website regularly to log your minutes of activity, set goals, and read information and resources available.</p> <p>Months 1-12 for both groups.</p> <p><b>Group 2:</b> Also at months 15, 18, 21, 24</p>                                                                                                                                                                                        | 10-20 minutes | <p>\$10 for each monthly survey completed.</p> <p><b>Group 2:</b><br/>-Potential to receive gifts based on your use of the website.</p> <p>\$5 for each month of study participation to help you with the cost of data usage on your cellphone related to receiving text messages from the study. \$120 total</p> |
| 6 Month Visit                                                | <p>-6 months after you begin the study, we will mail an activity monitor to your home. We will ask you to wear it for 7 days.</p> <p>-After one week, you will return the activity monitor.</p> <p>-At the visit, you will complete surveys.</p> <p>- We will measure your height, weight, waist circumference, blood pressure and body fat.</p> <p>-15 minute walk to demonstrate moderate intensity physical activity. We will also monitor and record your heart rate.</p> | 60-90 minutes | <p>\$25 for completing the visit</p> <p>\$10 for travel costs</p> <p>Child care reimbursement:<br/>\$7/hour 1 child, \$10/hour 2+ children (max of 2 hours)</p> <p><i>(Participants who complete by phone/online will get \$10)</i></p>                                                                           |
| 12 Month Visit                                               | <p>-12 months after you begin the study, we will mail an activity monitor to your home. We will ask you to wear it for 7 days.</p> <p>-After one week, you will return the activity monitor.</p> <p>-At the visit, you will complete surveys.</p> <p>- We will measure your height, weight, waist circumference, blood pressure and body fat.</p> <p>-15 minute walk to demonstrate moderate intensity</p>                                                                    | 60-90 minutes | <p>\$25 for completing visit</p> <p>\$10 for travel costs</p> <p>Child care reimbursement:<br/>\$7/hour 1 child, \$10/hour 2+ children (max of 2 hours)</p> <p><i>(Participants who complete by phone/online will get</i></p>                                                                                     |

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|                | physical activity. We will also monitor and record your heart rate.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                | \$10)                                                                                                                                                                                                                                                                                                                                                                                     |
| 18 Month Visit | <p>-12 months after you begin the study, we will mail an activity monitor to your home. We will ask you to wear it for 7 days.</p> <p>-After one week, you will return the activity monitor.</p> <p>-At the visit, you will complete surveys.</p> <p>- We will measure your height, weight, waist circumference, blood pressure and body fat.</p> <p>-15 minute walk to demonstrate moderate intensity physical activity. We will also monitor and record your heart rate.</p> <p><b>Group 1:</b> We will mail a survey for you to complete at home and bring into this visit.</p>                                                                                       | <p>60-90 minutes</p> <p>10-20 minutes</p>                      | <p>\$25 for completing visit</p> <p>\$10 for travel costs</p> <p>Child care reimbursement:<br/>\$7/hour 1 child, \$10/hour<br/>2+ children (max of 2 hours)</p> <p><b>Group 1:</b> \$10 for completing monthly questionnaire packet</p> <p><i>(Participants who complete by phone/online will get \$10)</i></p>                                                                           |
| 24 Month Visit | <p>-12 months after you begin the study, we will mail an activity monitor to your home. We will ask you to wear it for 7 days.</p> <p>-After one week, you will return the activity monitor.</p> <p>-At the visit, you will complete surveys.</p> <p>- We will measure your height, weight, waist circumference, blood pressure and body fat.</p> <p>-15 minute walk to demonstrate moderate intensity physical activity. We will also monitor and record your heart rate.</p> <p><b>Group 1:</b></p> <p>-We will mail a survey for you to complete at home and bring into this visit.</p> <p>-We will ask you to complete an additional questionnaire at the visit.</p> | <p>60-90 minutes</p> <p>10-20 minutes</p> <p>10-20 minutes</p> | <p>\$25 for completing visit</p> <p>\$10 to reimburse for travel costs</p> <p>Child care reimbursement:<br/>\$7/hour 1 child, \$10/hour<br/>2+ children (max of 2 hours)</p> <p><b>Group 1:</b><br/>\$10 for completing monthly questionnaire packet</p> <p>\$20 for completing extra survey.</p> <p><b>For Groups 1 and 2:</b><br/>\$50 bonus incentive for completing all follow-up</p> |

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|--|--|--|-------------------------------------------------------------------------------------------------------------------|
|  |  |  | visits in-person at months 6, 12, 18, 24.<br><br><i>(Participants who complete by phone/online will get \$10)</i> |
|--|--|--|-------------------------------------------------------------------------------------------------------------------|

- a. We may also ask to audio-record or monitor your in-person and telephone sessions with study staff. This is for training and quality control purposes only. Recordings will not contain any identifying information about you and will be labeled only with your study identification number. These recordings will be protected in the same way all study information is protected. The information will only be available to authorized researchers and staff. These recordings will be kept indefinitely. All audiotaping is optional. You have the right to ask that the recording be stopped or erased at any time.

## 5. What are the risks?

Participation in this study may involve some added risks or discomforts. You will receive information on health behaviors such as diet and exercise. Increasing your physical activity can have great benefits. However, there is always some risk with exercise. You may find exercising uncomfortable. You could have muscle soreness. You could fall, suffer a sprain, or bone injury. You should take precautions to avoid injuries. When exercising, some people have had heart attacks and sudden death related to heart problems. However, this is very rare. If you experience any injury or illness related to your participation in this project, please call the project coordinator, Vanessa Palomo at 401- 863-6556. There will also be a place on the website to report an injury or illness due to your participation in the study.

Because this is a research study, there may be some unknown risks that we do not know at this time. We will tell you of any significant new findings.

Your body fat will be measured using the Bioelectrical Impedance Analysis. This procedure requires that a small electrode be placed on your hand, wrist, ankle, and foot. A low-level signal is transmitted between electrodes. This not harmful to you and you will not feel it.

## What if you are injured during the study?

If you are injured as a direct result of your participation in this research, report the injury to us. You should call the project coordinator, Vanessa Palomo at 401-863-6556 or report the injury via the link on the study website. We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care. Brown University will not provide any other form of compensation to you if you are injured.

## 6. What are the benefits?

We cannot guarantee any direct benefit from participating in this study. You will receive information about physical activity and other health behaviors. From joining this study, you may increase your health knowledge and become motivated to exercise more. If you do make these changes, you could improve your health. Your participation may also help us create a program to help other Latina women become more physically active.

## 7. How will my information be protected?

Your participation in this study is confidential. Your answers to the surveys, the measurements taken at your visits, and the information you log on the study website will be kept confidential. Any forms you sign or papers you fill out will be kept in locked file drawers. No identifiable information will be collected online and data downloaded from online questionnaires will be stored in a secure study database. All computerized study data is password protected and only accessible to study staff. Your name will not be used in any articles that may come out of the study. All of the data for this project will be handled according to Brown University Policy, Federal guidelines, National Health Institute's policies, and Rhode Island laws regarding confidentiality. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, *except as explained below*.

The Certificate cannot be used to resist a demand for information from personnel of the National Institutes of Health that sponsor the research project. The National Institutes of Health may ask for information for the purposes of auditing or program evaluation. The National Institutes of Health would not release your information to any other agency or group.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you give an insurer, medical care provider, or other person written consent to receive research information, then the researchers will release that information with your permission.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of neglect or abuse of children or elders, harm to yourself or others.

#### **8. Are there any alternatives to this study?**

If you choose to not join this study, you are free to join other wellness projects in the community or at Brown University.

#### **9. What if I want to stop?**

You can choose to participate or not participate in this study. If you choose not to participate, you can still participate in other health programs in the community or with Brown University.

If you decide to join the project, you may quit at any time. If you do not want to answer a certain survey question, you do not have to. If you decide not to participate, there will be no penalty. It will not affect your relationship with Brown University or the organization from which you were recruited. The Principal Investigator may remove you from the study without your consent if she feels it is in your best interest or the best interest of the study. You may also be withdrawn from the study if you do not follow the instructions provided by the study staff.

You will be told if any important new information is found during the study that may affect your desire to continue.

**10. Who can I talk to if I have questions about this study?:**

If you have any questions about your participation in this study, you can call the principal investigator, Dr. Bess Marcus at (401) 863-9858. For Spanish speaking participants, please contact project coordinator Rachelle Edgar (401) 863-6164.

**11. Who can I talk to if I have questions about my rights as a participant?**

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at [IRB@Brown.edu](mailto:IRB@Brown.edu).

**12. Consent to Participate:**

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

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Participant's Signature and Date / PRINTED NAME

- ☐ Yes, I agree to have the sessions audio recorded and understand my rights as described.  
☐ No, I do not agree to have the sessions audio recorded.

- Participant Initials \_\_\_\_\_
- Staff Initials \_\_\_\_\_

**Permission to Re-Contact:**

\_\_\_\_ (initials) I give permission for researchers to contact me in the future for similar research studies.

\_\_\_\_ (initials) I do NOT give permission for researchers to contact me in the future for similar research studies.